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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,254	05/07/1999	WOLF-GEORG FORSSMANN	FORSSMANNETA	9824

7590 03/22/2002

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/22/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,254

Applicant(s)

FORSSMANN ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The amendment filed on 1/7/02 has been entered into the record. Claim 1 is amended. Claims 1, 4-9 and 11-13 are pending in the application.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

3. The rejections under 35 U.S.C. 112, first paragraph and second paragraph are maintained for the reasons of record as set forth in the previous office action.

Applicant states that the self explanatory Declaration of Dr.Schulz-Knappe answers the enablement and second paragraph issues. However, the office finds that the Declaration of Dr.Schulz-Knappe explains the general use of the various terminologies used in the field but does not show support for the enablement issues raised by the office especially a method for detecting pathogenic and non-pathogenic status in a given sample. Applicant gives explanation of various issues raised under 112, second paragraph. Such explanation is not supported by the claims. In other word, applicant is arguing the limitations, which are not present in the claim. For example;

Applicant explains the "condition of organism" can be good or bad. However, this method is to detect a pathogenic or any other condition of an organism. First of all "organism" could include E.coli. which indicates the "normal condition" of bacteria. Therefore, what is the pathogenic condition of an E.coli?

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Organism includes, per se a virus, therefore, what is the pathogenic condition of a virus? And what are the combinations?

Organism reads on using an intact and complete animal such as human, then how such an organism detected by this method?

Further, it is not clear how low molecular weight peptide define the pathogenic condition directly? The term "such as" renders the claim indefinite. Similarly the terms "reference", "representative" "defined controls" and "peptide display" are confusing.

4. Rejection of claims 1, 4, 8, 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Harry et al, 1989 (Clinical Microbiology Reviews, Vol 2, pages 241-249) is maintained for essentially the same reasons as the rejections of claims 1-4, 8, 10, 12 and 13 under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed on 1/7/02 have been fully considered but they are not deemed to be persuasive. Applicant

Applicant argues that the amendment to the claims and the Declaration is sufficient to overcome the rejection. Since the amendment introduced new matter (substantially entirety) and the Declaration does not address the prior art, the rejections of record are maintained. Applicant states that Harry et al does not measure all the peptides. It is the examiner's position that the sample used in the prior art does contain all the peptides and p24 analysis detects the high as well as low molecular weight peptides (immunoblot) such as p24 and depending on the amount of the p24 antigen, stage of infection could be diagnosed. Since the claimed invention is not clearly recited by the claims and is so broadly written, the prior art anticipates the claimed invention.

In response to applicant's argument that the references fail to show certain features of the disclosed invention, it is noted that the features upon which applicant relies (i.e., peptide

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function; direct measurement; relevance to individual condition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). And also specification does not teach detecting a pathogenic or any other condition of organism from the group consisting of prokaryote, eukaryote, multicellular organism, cells from tissue culture and cells from animals and humans, genetically engineered organism, genetically transformed organism and a conditioned organism. Further applicant gives examples and how to know the physiological role of peptides in the present 2/12/01 response in pages 7-8. Since there is no teaching of any disease in the specification, this argument is not found persuasive.

5. Rejection of claims 1,4, 8 under 35 U.S.C. 102(b) as being anticipated by Ausubel et al 1995 (Short Protocols In Molecular Biology, Chapter on analysis of proteins) is maintained for essentially the same reasons as the rejections of claims 1-4, 8, 10, 12 and 13 under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed on 1/7/02 have been fully considered but they are not deemed to be persuasive. Applicant

Applicant argues that the amendment to the claims and the Declaration is sufficient to overcome the rejection. Since the amendment introduced new matter (substantially entirety) and the Declaration does not address the prior art, the rejections of record are maintained. Applicant states that Ausubel et al does not measure all the peptides. It is the examiner's position that the claim 1 is so broad that any method such as the method described by Austell would read on the claims. Since the term condition is not clear, the prior art anticipates the claimed invention

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In response to applicant's argument that the references fail to show certain features of disclosed invention, it is noted that the features upon which applicant relies (i.e., condition/status of an individual, references from other organisms; characterization of low molecular weight or dipeptides) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since there is no teaching of any disease in the specification, this argument is not found persuasive.

6. Rejection of claims 1, 4-9 and 11-13 under 35 U.S.C. 102(b) as being anticipated by Jimenez et al 1994 (Journal of Neurochemistry; Vol. 62; pages 404-407) is maintained for essentially the same reasons as the rejections of claims 1- 13 under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed on 1/7/02 have been fully considered but they are not deemed to be persuasive. Applicant

Applicant argues that the amendment to the claims and the Declaration is sufficient to overcome the rejection. Since the amendment introduced new matter (substantially entirety) and the Declaration does not address the prior art, the rejections of record are maintained. Applicant states that Jimenez et al does not disclose the claimed invention rather discloses a method, which identifies high molecular weight substances. Further he argues that Jimenez's method does not disclose the condition of organism. Since the term condition is not clear and the claims are broad this prior art applies as it detects low molecular weight peptides. Since there is no teaching of any disease in the specification, this argument is not found persuasive.

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New Rejections Based on Amendment

7. The amendment filed 1/7/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 1, "substantially the entirety" and 'sbustantially of the detected". Applicant is required to cancel the new matter in the reply to this Office Action.

8. Claims 1, 4-9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the recitation of "substantially the entirety" and 'substantially of the detected" in claim 1. This is a new matter rejection.

9. Claim1 is objected to because of the following informalities: Spellings for 'procarvote", "eucarvote" are not correct. The spelling "Prokaryote" and "eukaryote" is suggested.

Appropriate correction is required.

10. Claim 1 is rejected as being vague and indefinite for the recitation of "substantially" What are the metes and bounds of substantially?

Claim 1 confusing for the recitation of "substantially of the detected"

Status of Claims

11. No claims are allowed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

3/17/02



MARK NAVARRO
PRIMARY EXAMINER